

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

| | |
|------------------------|------------------------------|
| Application Number | 10/565,763 |
| Filing Date | June 5, 2006 |
| First Named Inventor | Vincenzo De Leo |
| Art Unit | 1649 |
| Examiner Name | Christina M. Borgeest, Ph.D. |
| Attorney Docket Number | SER.105 |

Sheet 1 of 2

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|---|--------------------------------|--|---|
| | | Number - Kind Code ² (if known) | | | |
| | U1 | US-5,508,261 | 04-16-1996 | Moyle <i>et al.</i> | All |
| | U2 | US-5,405,945 | 04-11-1995 | Boime <i>et al.</i> | All |
| | U3 | US- | | | |
| | U4 | US- | | | |
| | U5 | US- | | | |
| | U6 | US- | | | |
| | U7 | US- | | | |
| | U8 | US- | | | |
| | U9 | US- | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ³ |
|--------------------|-----------------------|---|--------------------------------|--|---|----------------|
| | | Country Code ⁴ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | F1 | WO 01/58493 | 08-16-2001 | Maxygen APS | All | |
| | F2 | | | | | |
| | F3 | | | | | |
| | F4 | | | | | |
| | F5 | | | | | |
| | F6 | | | | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

| | |
|------------------------|------------------------------|
| Application Number | 10/565,763 |
| Filing Date | June 5, 2006 |
| First Named Inventor | Vincenzo De Leo |
| Group Art Unit | 1649 |
| Examiner Name | Christina M. Borgeest, Ph.D. |
| Attorney Docket Number | SER.105 |

Sheet 2 of 2

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| | R1 | CHAPPEL, S. <i>et al.</i> "Follicle stimulating hormone and its receptor: future perspectives" <i>Human Reproduction</i> , 1998, pp. 18-35, Vol. 13, No. 3. | |
| | R2 | LIU, C. <i>et al.</i> "Site-directed Alanine Mutagenesis of Phe ⁴³ , Arg ⁴⁵ , and Arg ⁴² -Ser ⁴³ -Lys ⁴⁴ in the Human Gonadotropin α -Subunit" <i>The Journal of Biological Chemistry</i> , October 15, 1993, pp. 21613-21617, Vol. 268, No. 29. | |
| | R3 | YOO, J. <i>et al.</i> "COOH-terminal Amino Acids of the α Subunit Play Common and Different Roles in Human Choriogonadotropin and Folitropin" <i>The Journal of Biological Chemistry</i> , June 25, 1993, pp. 13034-13042, Vol. 268, No. 18. | |
| | R4 | ROTH, K. E. <i>et al.</i> "Scanning-alanine mutagenesis of long loop residues 33-53 in follicle stimulating hormone beta subunit" <i>Molecular and Cellular Endocrinology</i> , 1995, pp. 143-149, Vol. 109. | |
| | R5 | VALOVE, F. M. <i>et al.</i> "Receptor Binding and Signal Transduction are Dissociable Functions Requiring Different Sites on Follicle-Stimulating Hormone" <i>Endocrinology</i> , 1994, pp. 2657-2661, Vol. 135, No. 6. | |
| | R6 | GROSSMAN, M. <i>et al.</i> "Site-Directed Mutagenesis of Amino Acids 33-44 of the Common α -Subunit Reveals Different Structural Requirements for Heterodimer Hormones and Suggests that Cyclic Adenosine 3', 5'-Monophosphate Production and Growth Promotion are Potentially Dissociable Functions of Human Thyrotropin" <i>Molecular Endocrinology</i> , 1996, pp. 769-779, Vol. 10, No. 6. | |
| | R7 | | |
| | R8 | | |
| | R9 | | |
| | R10 | | |
| | R11 | | |
| | R12 | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.